

Under the Paperwork reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

### INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	1	of	5
-------	---	----	---

**Complete if Known**

<b>Application Number</b>	10/811,343
<b>Filing Date</b>	03-26-04
<b>First Named Inventor</b>	Cook
<b>Art Unit</b>	
<b>Examiner Name</b>	
<b>Attorney Docket Number</b>	003433-000492

## U.S. PATENT DOCUMENTS

Examiner Initial *	Cite No. 1	Document Number Number Kind Code? (if known)	Publication Date MM-DD-YY	Name of Patentee or Applicant of Cited Document	Pages, columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1	US-3316401	10-10-67	Barat et al.	
	2	US-3649183	03-14-72	McCusker	
	3	US-4193813	03-18-80	Chvapil	
	4	US-4320201	03-16-82	Berg et al.	
	5	US-4394370	07-19-83	Jeffries	
	6	US-4404970	09-20-83	Sawyer	
	7	US-4409332	10-11-83	Jeffries et al.	
	8	US-4472840	09-25-84	Jeffries	
	9	US-4681588	07-21-87	Ketharanathan	
	10	US-4755593	07-06-88	Lauren	
	11	US-4798611	01-17-89	Freeman	
	12	US-4801299	01-31-89	Brendel et al.	
	13	US-4813958	03-21-89	Dixon	
	14	US-4837379	06-06-89	Weinberg	
	15	US-4838888	06-13-89	Nashef	
	16	US-4885005	12-06-89	Nashef et al.	
	17	US-4891359	01-02-90	Saferstein et al.	
	18	US-4969912	11-13-90	Kelman et al.	
	19	US-4976733	12-11-90	Girardot	
	20	US-5024841	06-18-01	Chu et al.	

## FOREIGN PATENT DOCUMENTS

[illegible]

Examiner Signature	Date Considered
-----------------------	--------------------

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include of this form with next communication to applicant.

1. Applicant's unique citation designation number (optional) 2. See Kinds codes of USPTO patent Documents, at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04.  
3. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3.) 4. For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6. Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 36 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450 Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.

SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786.9199) and select option 2.*

Under the Paperwork reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

### INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	2	of	5
-------	---	----	---

**Complete if Known**

<b>Application Number</b>	10/811,343
<b>Filing Date</b>	03-26-04
<b>First Named Inventor</b>	Cook
<b>Art Unit</b>	
<b>Examiner Name</b>	
<b>Attorney Docket Number</b>	003433-000492

## U.S. PATENT DOCUMENTS

Examiner Initial *	Cite No.	Document Number Number Kind Code? (if known)	Publication Date MM-DD-YY	Name of Patentee or Applicant of Cited Document	Pages, columns, Lines, Where Relevant Passages or Relevant Figures Appear
	22	US-5094661	03-10-92	Levy et al.	
	23	US-5106949	04-21-92	Kemp et al.	
	24	US-5171574	12-15-92	Kuberasampath et al.	
	25	US-5206023	04-27-93	Hunziker	
	26	US-5215541	06-01-93	Nashief et al.	
	27	US-5256418	10-26-93	Kemp	
	28	US-5279612	01-18-94	Eberhardt	
	29	US-5352463	10-04-94	Badylak et al.	
	30	US-5368608	11-29-94	Levy et al.	
	31	US-5374515	12-20-94	Parenteau et al.	
	32	US-5411887	05-02-95	Sojander	
	33	US-5413791	05-09-95	Rhee et al.	
	34	US-5447536	09-05-95	Girardot et al.	
	35	US-5456693	10-10-95	Conston et al.	
	36	US-5476516	12-19-95	Seifler et al.	
	37	US-5510121	04-23-96	Rhee et al.	
	38	US-5510418	04-23-96	Rhee et al.	
	39	US-5512291	04-30-96	Li	
	40	US-5522840	06-04-96	Krajcek	
	41	US-5693085	12-02-97	Buime et al.	

## FOREIGN PATENT DOCUMENTS

[illegible]

Examiner  
Signature

Date  
Considered

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not Considered. Include of this form with next communication to applicant.

1. Applicant's unique citation designation number (optional) 2. See Kind codes of USPTO patent Documents, at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04

3. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3.) 4. For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5. Kind of document by the appropriate symbols as indicated on the document under W IPO Standard ST.16 if possible. 6. Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1460 Alexandria, VA 22313-1460. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.

SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786.9199) and select option 2.*

Under the Paperwork reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

### INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet	3	of	5
-------	---	----	---

**Complete if Known**

<b>Application Number</b>	10/811,343
<b>Filing Date</b>	03-26-04
<b>First Named Inventor</b>	Cook
<b>Art Unit</b>	
<b>Examiner Name</b>	
<b>Attorney Docket Number</b>	003433-000492

## U.S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

[illegible]

Examiner  
Signature

Date  
Considered

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not Considered. Include of this form with next communication to applicant.

1. Applicant's unique citation designation number (optional) 2. See Kinds codes of USPTO patent Documents, at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04.  
3. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3.) 4. For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.f 16 if possible. 6. Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450 Alexandria, VA 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.**

SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

*If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786.9199) and select option 2.*

Under the Paperwork reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 4 of 5

**Complete if Known**

Application Number	10/811,343
Filing Date	03-26-04
First Named Inventor	Cook
Group Art Unit	
Examiner Name	
Attorney Docket Number	003433-000492

**OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS**

Examiner Initial *	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T 2
	45	Acell, Incorporated et al.'s Appeals from the U.S. District Court, ND of Indiana in case No. 4:03CV0046.	
	46	Badylak, S.F. et al.: "The Use of Xenogeneic Small Intestinal Submucosa as a Biomaterial for Achilles's Tendon Repair in a Dog Model", Journal of Biomedical Materials Research, Vol. 29, No. 8, 1995, pp. 977-985, XP002071882	
	47	Cobb, M.S. et al.: "Histology After Dural Grafting With Small Intestinal Submucosa", Surgical Neurology, Vol. 46, No. 4, 1996, pp. 389-394, XP00201883	
	48	Cross Appellant Cook Biotech Incorporated's Brief in Support of Cross-Appeal of Judgment of Non-Willfulness, Invention and No Relief for Infringement, and in Opposition to Appellants' Markman Appeal, U.S. District Court, ND of Indiana in case No. 4:03CV0046.	
	49	Cross-Appellant Purdue Research Foundation's Brief in Support of Cross-Appeal of Judgment, and in Opposition to Appellants' Markman Appeal, U.S. District Court, ND of Indiana in case No. 4:03CV0046.	
	50	D Horak et al: "Hydrogels in endovascular embolization. III. Radiopaque spherical particles, their preparation and properties: Biomaterials, GB, Elsevier Sciences Publishers BV., Barking, vol.2, no.8 03/01/1987 pgs.142-145	
	51	Defendants' Post-Hearing Markman Memorandum, Cook Biotech Incorporated et al. v. ACell et al., USDC ND IN Case No. 4:03CV0046.	
	52	European Search Report EP 08008810 dated June 27, 2008.	
	53	European Search Report, Patent Application No. 08012454.8	
	54	Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices; December 1987, Prepared by Center for Drug Evaluation and Research, Center for Biologic Evaluation and Research, Center for Devices and Radiological Health, and Center for Veterinary Medicine.	
	55	Hodde, J.P. et al., "Glycosaminoglycan Content of Small Intestinal Submucosa: A Bioscaffold for Tissue Replacement" Tissue Engineering, Vol. 2, No. 3, 1996, pp. 209-217 XP002063373	

Examiner  
Signature

Date

Considered

\* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1. Applicants unique citation designation number. (optional) 2. Applicant is to place a check mark here if English language translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450 Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.

SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Substitute for form 1449B/PTO

(Use as many sheets as necessary)

Sheet	5	of	5
-------	---	----	---

**Complete if Known**

<b>Application Number</b>	10/811,343
<b>Filing Date</b>	03-26-04
<b>First Named Inventor</b>	Cook
<b>Group Art Unit</b>	
<b>Examiner Name</b>	
<b>Attorney Docket Number</b>	003433-000492

## OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

[illegible]

Examiner  
Signature

Date  
Considered

1. Applicants unique citation designation number. (optional) 2. Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450 Alexandria, VA 22314-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS.

SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.